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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,089	04/23/2004	Craig Jordan	50229-436	7583

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/830,089	JORDAN, CRAIG	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Claims 19 and 21 are given priority to patent application 09/799100 filed on 3/6/2001, as the subject matter is not found in the provisional applications disclosed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19-21 recites the limitation "the method according to claim 18" while there is no method of claim 18. There is insufficient antecedent basis for this limitation in the claim.

3. Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are unknown since there is lack of antecedent basis of the method.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 11-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Broudy et al. (US 5,489,516) and in view of Koubek et al. (*Eur. J. Haematol.* **1999**, *63*, 1-10) and Voisin et al. (US 4,340,535).

6. Broudy et al. (5,489,516) discloses the method of purifying hematopoietic cells by exposing a mixture of cells to monoclonal antibodies coupled to a cytotoxic agent, such as radioisotope ^{125}I then separating cells that bind to the monoclonal antibody, such as IgG2α from those that do not and also for removing tumor cells (leukemia cells) by labeling them with a biotin, phycoerythrin, methotrexate, plant toxin (ricin) or fluoresceine isothiocyanate label (column 3, lines 24-26; column 6-7; column 2, lines 5-37; column 14, line 58; column 15, lines 1-8). The antibodies can be coupled to radioisotopes such as ^{212}Bi (example 7). The mixture of cells to be exposed to the monoclonal antibody can be bone marrow cells, blood cells, or tissue cells (column 6, lines 1-12). This method can be useful in inhibiting the growth or development of neoplastic cells and the dosage employed to a patient is varied based on the severity of the condition (column 7, lines 18-27; column 9, lines 4-17). Broudy et al. (5,489,516) does not teach of an antibody conjugate that selectively binds to CD123.

7. Koubek et al. (*Eur. J. Haematol.* **1999**, *63*, 1-10) discloses the analysis of the reactivity of monoclonal antibodies against cells derived from patients with leukemia and lymphomas, such as non-Hodgkin's lymphoma and assays thereof (p1, paragraph 2; p2, patients). The pathological cells used were peripheral blood and bone marrow and the monoclonal antibodies used were IL-2Rα (p2, cells; p3, paragraph 2).

8. Voisin et al. (US 4,340,535) discloses the coupling of ricin with an antibody which is capable of recognizing a given antigen then the antibody conjugate was administered to mice that had been previously transplanted with lymphoma cells (abstract; column 30, lines 49+)

9. At the time of the invention it would have been obvious to one ordinarily skilled in the art to combine the disclosure of a radiolabelled antibody and its method of separating leukemic progenitor cells from bone marrow cells by Broudy et al. (5,489,516) and its administration to patients to do the same with the disclosure of Koubek et al. (*Eur. J. Haematol.* **1999**, *63*, 1-10) of a CD123 specific antibody IL-2Rα and Voisin et al. (US 4,340,535) to determine the central role these cells play in generating and perpetuating human leukemic disease and define their biological properties.

10. Claims 11-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Broudy et al. (5,489,516) in view of Lopez et al. (WO 97/24373).

11. Broudy et al. (5,489,516) discloses the method of purifying hematopoietic cells by exposing a mixture of cells to monoclonal antibodies coupled to a cytotoxic agent, such as radioisotope ^{125}I then separating cells that bind to the monoclonal antibody, such as IgG2α from those that do not and also for removing tumor cells (leukemia cells) by labeling them with a biotin, phycoerythrin, methotrexate, plant toxin (ricin) or fluoresceine isothiocyanate label (column 3, lines 24-26; column 6-7; column 2, lines 5-37; column 14, line 58; column 15, lines 1-8). The antibodies can be coupled to radioisotopes such as ^{212}Bi (example 7). The mixture of cells to be exposed to the

monoclonal antibody can be bone marrow cells, blood cells, or tissue cells (column 6, lines 1-12). This method can be useful in inhibiting the growth or development of neoplastic cells and the dosage employed to a patient is varied based on the severity of the condition (column 7, lines 18-27; column 9, lines 4-17). Broudy et al. (5,489,516) does not teach of an antibody conjugate that selectively binds to CD123.

12. Lopez et al. (WO 97/24373) discloses a 7G3 monoclonal antibody that selectively binds CD123 and that may be suitable for treating myeloid leukemias, lymphomas, such as follicular B cell lymphomas (abstract; p6, lines 8-13). MoAb 7G3 antagonizes the proliferation of the leukemic cells (p2, lines 34+). Radioiodination of MoAb 7G3 and binding assays were performed for the analysis of binding curves (examples).

13. At the time of the invention it would have been obvious to one ordinarily skilled in the art to combine the disclosure of a radiolabelled antibody and its method of separating leukemic progenitor cells from bone marrow cells by Broudy et al. (5,489,516) and its administration to patients to do the same with the disclosure of Lopez et al. (WO 97/24373) of a CD123 specific antibody MoAb 7G3 to inhibit the growth or development of neoplastic cells, determine the central role these cells play in generating and perpetuating human leukemic disease and define their biological properties.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
June 27, 2006

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER